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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

MARX, I

ART UNIT

PAPER NUMBER

1651

10

DATE MAILED:

04/13/01

Please find below and/or attached an Office communication concerning this application or proceeding:

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/331,759

Applicant(s)

Higashiyama et al.

Examiner

Irene Marx

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 26, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-12, and 14-38 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-12, and 14-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 20) ☐ Other: _____

The application should be reviewed for errors. Error occurs, for example, in the spelling of "soy beams" in claim 33; "cetrifugation" in claim 35; "phosphsphase" at line 2 and "sale" at line 7 in claim 28. Error occurs also in claim 1 which appears incomplete.

The amendment filed 2/26/01 is acknowledged. Claims 1-3, 6-12, and 14-38 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6-12, and 14-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague indefinite and confusing in that the claim appears incomplete and truncated as well as grammatically incorrect. The phrase

"wherein the balance of the pellet form and the pulp form of the microorganism is controlled by adjusting the concentrations of phosphate ions, potassium ions, sodium ions, magnesium unsaturated fatty acids by the microorganism is enhanced."

is not understood. It is unclear what is intended by "magnesium unsaturated fatty acids"

It is unclear how a "balance" of these forms is produced or the significance of such a "balance" or of such "forms". What are "pulp form" and "pellet form"? These are not clearly terms of art. How are the forms "controlled", and for what purpose? No clear correlation is apparent between "control" and fatty acids production? In which way? Is the "adjustment" up or down?

In addition, it is unclear what is encompassed by the "controlled by adjusting", since there is no indication how the adjustment or control is to be achieved.

Also, the metes and bounds of "subgenus *Mortierella*" are not readily apparent to one of ordinary skill in the art.

Claim 1 is confusing in the recitation of "enhanced". The extent of enhancement is unclear, particularly in the absence of a recovery step for the product produced.

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

Inasmuch as claim 1 is incomplete, claims 2-3 and 7 dependent thereon lack antecedent basis for example, for "calcium ions".

Claims 21 and 22 are vague, indefinite and confusing in that the culture medium ingredients appear to be closed and limited to phosphate, sodium, magnesium and calcium ions in certain ranges. Yet the claims are, at the same time, open to further ingredients in that the culture medium "comprises" a nitrogen and a carbon source.

Claim 7, 12 and 30 are/remain confusing with respect to the language "Mead acid". Applicant's indication that this is the "common name" of the product is noted. Insertion of the chemical name would be remedial.

Claim 29 is redundant in the parenthetical recitation of formulae, which should be deleted.

Claims 23 and 38 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 35 is vague, indefinite and confusing and encompasses an improper Markush grouping because it is unclear which processing procedures are to be used together and which are intended in the alternative. The phrase "or combinations thereof, together with any of the above treatments" is not understood. See MPEP 2173.05(h)(a). The intended meaning of "water solvents" is not readily apparent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-22 and 38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sigma Catalogue.

Sigma Catalogue disclose a medium suitable for culturing fungi which appears to be identical to the presently claimed medium (see, e.g., page 286) . Consequently, the claimed medium appears to be anticipated by the reference.

However, even if the reference medium and the claimed medium are not one and the same and there is, in fact, no anticipation, the reference medium would, nevertheless, have rendered the claimed medium obvious to one of ordinary skill in the art at the time the claimed invention was made since the media have the same basic constituents in substantially the same concentrations and are each clearly suitable for culturing members fungi of the subgenus *Mortierella*, for example. In addition, it would have been within the purview of the skilled artisan in the microbiological arts to adjust the concentration of essential ions for optimization purposes.

Thus, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly

owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6-12, and 14-38 are remain rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki *et al. et al.* taken with Manoh *et al.* and Yamaguchi *et al.* (US 5,015,579) for the reasons as stated in the last Office action and the further reasons below.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants did not address claims 21-23 and 38 specifically. Each of Suzuki *et al.*, Manoh *et al.* and Yamaguchi *et al.* discloses a culture medium which contains phosphate, sodium, magnesium and calcium ions in ranges which appear to be within the claimed ranges. See, e.g., Examples 1 and 3; col. 5; Examples 1-2, respectively. However, even if the claimed culture medium is not identical to the referenced a culture medium with regard to phosphate, sodium, magnesium and calcium ions content, the adjustment of ions such as phosphate, sodium, magnesium and calcium ions for optimization purposes in culture media for the cultivation of microorganisms would have been within the ordinary skill of the art, since this is the essence of biotechnical engineering. The intended use of the culture medium does not distinguish the culture medium since such undisclosed use is inherent in the culture media taught by the references. In order to be limiting, the intended use must create a structural difference between the claimed medicament and the prior art medicament. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). When applicant claims a "composition in terms of function . . . and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection" (MPEP 2112).

Applicants argue broadly that the references are not directed to members of the subgenus *Mortierella*. However, applicants have not established that the study published in the Amano *et al.* reference is definitive to one of ordinary skill in this art regarding taxonomy of *Mortierella*.

In any event the disclosure of Suzuki *et al.* regarding the adjustment of ions in the media is deemed relevant to the cultivation of any member of the genus *Mortierella*, regardless of the subgenus.

As to the balance of "pellet form" and "pulp form", it is unclear what is intended by this terminology. In addition, the results presented in the instance specification pertain to specific members of specific species, and not with any specificity to all members of the subgenus *Mortierella*. The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

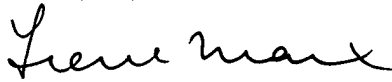
Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196 .


Irene Marx
Primary Examiner
Art Unit 1651